



**ENVIRONMENTAL PROTECTION AGENCY**

6560-50

**[EPA-HQ-OPPT-2010-1010; FRL-9511-5 ]**

**Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: *TSCA Section 4 Test Rules, Consent Orders, Enforceable Consent Agreements, Voluntary Testing Agreements, Voluntary Data Submissions, and Exemptions from Testing Requirement* (EPA ICR No. 1139.09, OMB No. 2070-0033). The ICR, which is abstracted below, describes the nature of the information collection activity and its expected burden and costs.

**DATES:** Additional comments may be submitted on or before [insert date 30 days after publication in the Federal Register].

**ADDRESSES:** Submit your comments, referencing docket ID Number EPA-HQ-OPPT-2010-1010 to (1) EPA online using [www.regulations.gov](http://www.regulations.gov) (our preferred method), by email to [oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov) or by mail to: Document Control Office (DCO), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Mail Code: 7407T, 1200 Pennsylvania Ave., NW, Washington, D.C. 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17<sup>th</sup> Street, NW, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Maryann Petrole, Director, Environmental Assistance Division, Office of Pollution Prevention and Toxics, Environmental Protection

Agency, Mail code: 7408-M, 1200 Pennsylvania Ave., N.W., Washington, DC 20460; telephone number: 202-554-1404; e-mail address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On August 10, 2011 (76 FR 49471), EPA sought comments on this renewal pursuant to 5 CFR 1320.8(d). EPA received one supportive comment during the comment period, which did not result in any substantive change to the Supporting Statement. Any additional comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA EPA-HQ-OPPT-2010-1010, which is available for online viewing at <http://www.regulations.gov>, or in person inspection at the OPPT Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202-566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is 202-566-0280. Use [www.regulations.gov](http://www.regulations.gov) to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select “search,” then key in the docket ID number identified above.

EPA’s policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in [www.regulations.gov](http://www.regulations.gov) as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. When EPA identifies

a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in [www.regulations.gov](http://www.regulations.gov). The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in [www.regulations.gov](http://www.regulations.gov). For further information about the electronic docket, go to [www.regulations.gov](http://www.regulations.gov).

**Title:** TSCA Section 4 Test Rules, Consent Orders, Enforceable Consent Agreements, Voluntary Testing Agreements, Voluntary Data Submissions, and Exemptions from Testing Requirement.

**ICR Status:** This is a request to renew an existing approved collection. This ICR is scheduled to expire on April 30, 2012. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

**Abstract:** This ICR covers the submission of test data to the Environmental Protection Agency (EPA) to support the decision making process for an industrial chemical under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601). Under TSCA, EPA has the authority to issue regulations designed to gather health/safety and exposure information on, require testing of, and control exposure to chemical substances and mixtures. Drugs, cosmetics, foods, food additives, pesticides, and nuclear materials are exempt from TSCA.

Under TSCA section 4, EPA must assure that appropriate tests are performed on a chemical if it decides: (1) that a chemical being considered under TSCA section 4(a) may pose an "unreasonable risk" or is produced in "substantial" quantities that may result in substantial or significant human exposure or substantial environmental release of the chemical; (2) that

additional data are needed to determine or predict the impacts of the chemical's manufacture, processing, distribution, use or disposal; and (3) that testing is needed to develop such data.

In general, when the need for data is identified by EPA, EPA may obtain the needed test data (1) by issuing a test rule through notice and comment rulemaking, (2) through negotiation with industry and issuing an enforceable consent agreement (ECA), or (3) through commitments from industry, i.e., voluntary testing agreements (VTAs). Industry may also submit test data to EPA on their own initiative.

EPA uses the information collected under the authority of TSCA section 4 to assess risks associated with the manufacture, processing, distribution, use or disposal of a chemical, and to support any necessary regulatory action with respect to that chemical.

The testing specified in a rule or consent order issued under TSCA section 4 only needs to be conducted once for each specified chemical. As such, only one of the entities that manufacture, import or process the specified chemical, or a consortia formed by these entities, is expected to conduct the specified testing and report the results of that testing to EPA. In addition, an entity subject to a test rule may apply for an exemption from the testing requirement if that testing will be or has been performed by another party.

This information collection applies to reporting and recordkeeping activities associated with the information that EPA requires industry to provide in response to TSCA section 4 test rules, consent orders or voluntary agreements, and other data submissions, as well as those related to the exemption applications. As such, responses to the collection of information are either mandatory if codified (see 40 CFR part 790), and voluntary when not.

Respondents may claim all or part of a response as CBI. EPA will disclose information that is covered by a CBI claim only to the extent permitted by, and in accordance with, the procedures in 40 CFR part 2.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

**Burden Statement:** The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 9 and 263 hours per response. Burden is defined in 5 CFR 1320.3(b).

*Respondents/Affected Entities:* Entities potentially affected by this ICR are manufacturers, processors, importers, users, distributors or disposers of one or more specified chemical substances.

*Frequency of Collection:* On occasion.

*Estimated Average Number of Responses for Each Respondent:* Varies by activity, but is estimated to range from 1 to 131 per respondent.

*Estimated Total No. of Respondents:* Varies by activity, but is estimated to range from 1 to 18.

*Estimated Total Annual Burden on Respondents:* 629,893 hours.

*Estimated Total Annual Costs:* \$13,289,461, with an additional \$9,628,441 for non-labor costs related to laboratory test costs.

**Changes in Burden Estimates:** This request represents an increase of 477,931 hours from that

currently in the OMB inventory (from 151,962 hours to 629,893 hours). This increase reflects several adjustments in the estimates related to a better break-out of the different activities for the covered collection and an adjustment in projected potential future activities regarding voluntary submissions. The Agency has also adjusted all unit costs to reflect the latest available labor wage rates and has identified the non-labor costs more clearly. The Supporting Statement provides details about the change in burden estimate. The change is an adjustment.

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John Moses, Director, Collection Strategies Division

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